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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,063	01/25/2000	Jane E. Polston	UF-232XC1	8057

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EXAMINER
SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/491,063	Applicant(s) POLSTON ET AL.	
	Examiner Mary Schmidt	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 15-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13 and 15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 1, 3-13 and 15-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 is drawn to the transgenic plant according to claim 9, wherein said transgenic plant is a hybrid made by crossing a transgenic plant comprising a polynucleotide that encodes a nonmutated geminivirus Rep protein, or a *fragment thereof*, with a plant that does not comprise a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a *fragment thereof*. Claim 20 is drawn to the transgenic plant according to claim 9, wherein said transgenic plant is a hybrid made by crossing a first transgenic plant comprising a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a *fragment thereof*, with a second transgenic plant comprising a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a *fragment thereof*. Claim 21 is drawn to the transgenic plant according to claim 20, wherein said second transgenic plant is derived from a transformation event distinct from the transformation event from which said first transgenic plant is derived.

Claims 15-18 are further included in the instant rejection since they are drawn to a cell transformed with a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a *fragment thereof.*

MPEP 2163 teaches the following conditions for the analysis of the claimed invention at the time the invention was made in view of the teachings of the specification and level of skill in the art at the time the invention was made:

> **The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence....A lack of written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process....Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement....The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.**

In the instant case, the claims are drawn to fragments of Rep. The claims are not drawn to fragments of specific nucleic acid sequences, nor fragments of a particular size of known nucleic acid sequences, but any fragment of any sequence considered a Rep gene. As such, the claims

read on a broad scope of any possible nucleic acid fragment, and encompass sequences having at least 1 nucleic acid in common with any possible Rep gene. Since the specification as filed has not provided any guidance as to the size of fragments, other identifying features of such fragments by way of sequence structure, nor other guidance for detection of a representative number of species of any such fragment, one skilled in the art would not have been able to readily envision any fragment of Rep having the function of a Rep. The references cited in the previous Official Action, scope of enablement, rejection regarding the unpredictability in the art for discerning protein function from nucleic acid structure, further support a lack of correlation in the art for understanding the function of a nucleic acid sequence without significant identifying characteristics. One of skill in the art would not have recognized that Applicant was in possession of the breath of claimed fragments to Rep in view of the lack of description in the specification of the structures of a representative number of species of any such fragment as broadly claimed.

Claim Rejections - 35 USC § 102

3. Claims 1, 3, 5-6, 9-10, 12, 13, 15, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brunetti et al. (Molecular Plant-Microbe Interactions 10 (5):p571-579, 1997; IDS Reference AP) for the same reasons as set forth in the Official Action mailed 10/02/01.

Applicant's arguments filed 3/12/02 have been fully considered but they are not persuasive.

Claim 13 was inadvertently omitted from the prior rejection, but is now considered since it is drawn to the transgenic plant or plant tissue according to claim 9, wherein said plant tissue is a plant seed. Brunetti et al. taught on page 572 (col. B, line 25) for instance that "self-pollinated seed from plant 47 was harvested."

New claim 19 is drawn to the transgenic plant according to claim 9, wherein said transgenic plant is a hybrid made by crossing a transgenic plant comprising a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a fragment thereof, with plant that does not comprise a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a fragment thereof. Brunetti et al. taught on page 574 (line 11) that "hybrid progeny were obtained by fertilizing line 10 with pollen from line 47."

New claim 20 is drawn to the transgenic plant according to claim 9, wherein said transgenic plant is a hybrid made by crossing a first transgenic plant comprising a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a fragment thereof, with a second transgenic plant comprising a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a fragment thereof." Brunetti et al. taught on page 572, col. B, lines 25-30, that "self-pollinated seed from plant 47 was harvested and analyzed. T-Rep was easily detected in all the R1 seedlings analyzed (data not shown). However, R1 plants, from seeds germinated either on agar plates or in soil, did not grow properly, showed pronounced leaf curling and wilting, and most of them died within 2 to 4 weeks of germination." Thus, although the transgenic plants did

not survive, Brunetti et al. taught transgenic plants having the same parent and thus having both "parents" having the geminivirus Rep protein.

Applicant argues on page 6 of the response that the phenotypes of the plants taught by Brunetti et al. resulting from the transformed plants is not the same as the phenotype envisioned by Applicants' transformed plants as taught in the specification on page 10 and 11. In response, however, Applicant is arguing limitations not found in the claims, specific phenotypic characteristics.

MPEP 2111.01 taught that "[w]hile the meaning of claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow." Therefore, the claims as written are drawn to plants transformed with geminivirus Rep protein. The claims do not specify phenotypic characteristics of the resultant plants other than the fact that they have certain transformed nucleic acids. Therefore, the claims, given their broadest reasonable interpretation of any plant having the transformed geminivirus Rep protein, encompasses the plants taught by Brunetti et al.

Furthermore, MPEP 2112.01 taught that "[w]here the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." As such, since all the claimed limitations are taught by Brunetti et al.,

Brunetti et al. taught compositions and methods having the identical or substantially identical compositions and methods and thus a *prima facie* case of anticipation had been established.

4. Claims 1, 3-13 and 15-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Stout et al. (U.S. Patent 6,291,743 B2) for the same reasons as set forth in the Official Action mailed 10/02/01.

Applicant's arguments filed 3/12/02 have been fully considered but they are not persuasive.

Claim 13 was inadvertently omitted from the prior rejection, but is now considered since it is drawn to the transgenic plant or plant tissue according to claim 9, wherein said plant tissue is a plant seed. Stout et al. taught throughout the specification such as in col. 3, lines 3-19, seeds from transformed plants.

Claims 5, 12, and 17 were inadvertently omitted from the prior rejection, but are now considered since Stout et al. taught in col. 1, lines 56-60, that TYLCV is one of the geminivirus contemplated for making geminivirus-resistant transgenic plants such as in col. 5.

New claim 19 is drawn to the transgenic plant according to claim 9, wherein said transgenic plant is a hybrid made by crossing a transgenic plant comprising a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a fragment thereof, with plant that does not comprise a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a fragment thereof. New claim 20 is drawn to the transgenic plant according to claim 9, wherein said

transgenic plant is a hybrid made by crossing a first transgenic plant comprising a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a fragment thereof, with a second transgenic plant comprising a polynucleotide that encodes a non-mutated geminivirus Rep protein, or a fragment thereof." Claim 21 is drawn to the transgenic plant according to claim 20, wherein said second transgenic plant is derived from a transformation event distinct from the transformation event from which said first transgenic plant is derived."

Stout et al. taught plants having the self pollination of transgenic plants in col. 5. Thus, they taught transgenic plants having the same parent and thus having both "parents" having the geminivirus Rep protein. Stout et al. taught in col. 5 that "[g]eminivirus-resistant plants are incorporated into traditional breeding programs to develop elite breeding lines that include the resistance-conferring transgene." They thus taught hybrids from plants both having the resistance proteins and those not having the resistance proteins and generally taught multiple combinations of parent plants.

Applicants' traverse the rejection on page 7 of the response. Applicants' first argue that "the results disclosed therein regarding resistance of the transgenic plants to virus are not particularly meaningful and do not establish that virus resistant plants were obtained. For example, in the Stout et al. patent, resistance is not demonstrated for the entire life of the plant, but only for 32 days." In response, however, Applicant is arguing limitations not found in the claims, specific phenotypic characteristics. As argued above, MPEP 2111.01 requires that the claims be given their broadest reasonable interpretation. The claims do not specify phenotypic

characteristics of the resultant plants other than the fact that they have certain transformed nucleic acids. Therefore, the claims, given their broadest reasonable interpretation of any plant having the transformed geminivirus Rep protein, encompasses the plants taught by Stout et al. Furthermore, in view of MPEP 2112.01 (also recited above), since all the claimed limitations are taught by Stout et al., Stout et al. taught compositions and methods having the identical or substantially identical compositions and methods and thus a *prima facie* case of anticipation had been established.

Applicant further argues that "the constructs described in the Stout et al. patent for producing virus resistant transgenic plants encoded a mutated viral Rep protein. As noted in regard to the Rep protein used in the invention is not mutated." In response, the patent taught both plants with rep mutations and plants without rep mutations. For instance, in col. 2 and col. 3, section A generally teaches production of infectious clones; Table 1A in col. 6 teaches vectors made for transfecting plants where the gene is not mutated. As such, Stout et al. did teach all the instantly claimed limitations for transformation of non-mutated rep genes.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
June 3, 2002

SEAN McGARRY
PRIMARY EXAMINER
1635